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CONNOLLY BOVE LODGE & HUTZ LLP
1875 EYE STREET, N.W.
SUITE 1100
WASHINGTON, DC 20036

EXAMINER	
THOMAS, TIMOTHY P	

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1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/521,153	HALL, JAN	
	Examiner	Art Unit	
	Timothy P. Thomas	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of differentiation factors as the GSS specie in the reply filed on 12/17/2007 is acknowledged.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

3. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

4. The Swedish priority application, #0202316-6, filed 7/25/2002, has been received. However, since no English translation has been provided, the filing date of the PCT application, PCT/SE03/01107, filed 6/26/2003, has been used to determine prior art dates.

Specification

5. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

6. The disclosure is objected to because of the following informalities: There is no section "Brief Description of the Several Views of the Drawings".

Appropriate correction is required.

Claim Objections

7. Claim 3 is objected to because of the following informalities: The grammar in the phrase, "and in that, in the stage..." in the 4th line is incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1, on which all other claims depend, is drawn to "an arrangement for using bioactive or osteoinductive material...comprising an implant...GSS...arranged in or on the implant", which appears to be a product claim. However, in the last three lines of claim 1, the recited actions of GSS on or in the implant during a stage of incorporation of "passes into" and "interacts or integrates with" and "forms" are method steps required in the practice of this product claim. These required action steps mix a product and a process into the same claim, which does not fall into any of the statutory classes.

Applicant is advised that process steps in a product claim should be worded as characterizing the claimed product rather than being action step(s).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 1 provides for an arrangement for using bioactive or osteoinductive material to build up a bone-based lateral support for at least one implant arranged in a jaw bone hole, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

13. Claim 1 recites an abbreviation, GSS, without including its name in parentheses at the first occurrence in the claims. The recitation of the abbreviation, without being accompanied by its meaning, does not make clear the material referred to. Neither the reference to GSS as "growth stimulating substance or substances" in the disclosure (specification, p. 4, lines 7-8), nor the claim language are controlling of the meaning of GSS.

14. The recitation in claim 1 of a first "and" word along with a second "and/or" phrase connecting the recited GSS materials in the phrase "[i] matrix molecules, [ii] growth factors **and** [iii] differentiation factors **and/or** [iv] peptides with growth stimulating properties" does not make clear which of the first three materials is required in combination to fall within the metes and bounds of the claim; for instance, two different interpretations when selecting the "or" embodiment of the phrase could refer to the minimally required components of: 1) ([i] and [ii] and [iii]) or [iv]; or 2) [i] or ([ii] and [iii]) or [iv].

15. Claim 2 recites the "real" centerline of the jaw bone in the horizontal plane. It is not clear whether this is the same as the observed centerline or an extrapolation of the jaw line for tooth holes with defects, such as atrophied bone.

16. The term "greatly degenerated" in claim 4 is a relative term which renders the claim indefinite. The term "greatly degenerated" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

17. Claim 12 recites the unit is coated with GSS on its outer surface exposed toward the implant. However, Figure 4 depicts "a unit" covering the outer surface of the implant. A coating on the outer surface of this unit would not be exposed toward the implant. Therefore, the recitation of this claim is confusing, and does not make clear on which element the GSS is coated and/or on which surface.

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of the growth stimulating substances (GSS), "differentiation factors". The "differentiation factors" of claim 1 are directed to particular practices of passing into spaces, interacting or integrating with cells and forming a bone-based lateral support. It is not clear which of the generic differentiation factors known in the art will accomplish the actions as claimed. No compounds, peptides or proteins have been identified in the disclosure that would support the description of the genus "differentiation factors" with the claimed particular practices.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In*

> *re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to an arrangement for using bioactive or osteoinductive material to build up a bone-based lateral support for at least one implant arranged in an assigned jaw bone hole; the implant is arranged to be at least partially covered by soft tissue or by a unit applied to the jaw bone, forming at least one space into which cell-containing body fluid penetrates, wherein bioactive or osteoinductive material comprising GSS materials, including differentiation factors, arranged in or on the implant; the GSS material in a later stage (stage of incorporation) passeses into the spaces, interacts or integrates with the cells and thus forms a cone-based lateral support for the implant.

(1) Level of skill and knowledge in the art:

The level of skill and knowledge in the art is high

(2) Partial structure:

No structures or partial structures for any differentiation factor has been disclosed.

(3) Physical and/or chemical properties and (4) Functional characteristics:

No physical or chemical properties have been disclosed. The material in some way stimulates cell material to form a bone-based material that provides a lateral support. The claims recite particular practices of passing into spaces, interacting or integrating with cells and forming a bone-based lateral support.

(5) Method of making the claimed invention:

No methods of making any differentiation factor has been disclosed.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1-20 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any "differentiation factor". Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. The specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984)

(affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 1-4, 6-9, 11, and 14-17 are rejected under 35 U.S.C. 102(a) & (b) as being anticipated by Wikesjö, et al. ("Augmentation of Alveolar Bone and Dental Implant Osseointegration: Clinical Implications of Studies with rhBMP-2"; 2001; Journal of Bone and Joint Surgery; 83-A (Suppl. 1; Pt. 2): S136-45).

Wikesjö teaches the elements of the claims: the use of recombinant human bone morphogenic protein-2 (rhBMP-2) for alveolar bone augmentation and dental implant fixation (background); the use of rhBMP-2 in a successful carrier system allows the BMP to act as a differentiation factor (p. S1-138, right, 2nd paragraph); implants arranged in jaw bone holes are shown in Figure 1b, the model of the figure is named the "critical-size supraalveolar peri-implant defect model", and is useful for the study of

dental implant osseointegration (p. S1-138, 1st paragraph); the biomaterials used were mixed with autologous blood (a cell containing body fluid), then defects received various combinations that included rhBMP-2 (paragraph spanning pp. S1-138-9); implants placed in defects that received rhBMP-2 exhibited increased bone formation along the exposed implant surface compared to controls (p. S1-140, right, 1st paragraph); clinically significant vertical and horizontal gain of alveolar bone was observed upon application of rhBMP-2/decalcified bone matrix (DBM)/ blood onlay, followed by implant placement into the newly formed ridge (Figure 4; p. S1-141, right, 2nd paragraph). These arrangements involve an implant covered (at least partially) by soft tissue, wherein the implant forms spaces into which body fluid penetrates and bioactive/ osteoinductive material comprising matrix molecules (DMB, for example), growth factors (rhBMP-2 acts as a growth factor, see p. S1-141, 2nd paragraph) and a differentiation factor (rhBMP-2). Figure 7b and c shows implants in a position that is offset in relation to the centerline of the jaw, outer thread parts have greater degree of exposure on one side than the other; three and two implants arranged in the jaw bone are show in Figure 1b and 6a and 6b, two different irregular depths are apparent in Figure 6a, Figure 6b shows bone base lateral support has substantially filled the defects, both implants appear to have nearly the same degree of recessing after the stage of incorporation (figure 6b); implants extending in the vertical direction associated with "greatly" degenerated bone (5 mm) in the vertical direction is shown in Figure 1, the exposure of the implant outer surface extends about 50% in the height direction (a 10-mm implant inserted 5 mm leaves 5 mm exposed; Figure 1b), nearly identical vertical extension is

depicted in Figures 1b and 6b. With respect to claims 6-8, these claims limit details of one embodiment of the invention (where a unit is attached), but a second embodiment is still an option of these claims, dependent on claim 1; the claims are rejected with respect to the other embodiment (the implant covered by soft tissue).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. Claims 1, 5-8, 10, 12-13 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wikesjö, et al. ("Augmentation of Alveolar Bone and Dental Implant Osseointegration: Clinical Implications of Studies with rhBMP-2"; 2001; Journal of Bone and Joint Surgery; 83-A (Suppl. 1; Pt. 2): S136-45) and Pirhonen, et al. (US 2003/0105530 A1; 2003 Jun 5; filing date 2001 Dec).

Claim 1 is rejected as outlined above under 35 U.S.C. 102 (a) & (b). With respect to claims 5-8, 10, 12-13 and 18-20, Wikesjö does not teach a unit temporarily or

permanently attached to the jaw bone, nor an arrangement where the implant's outer surface exposed in the initial stage extends in the range of 20-180° (or 30-70°), nor different concentrations of GSS on the portions of the exposure than the other portions, nor a coating of the unit with GSS. Pirhonen teaches implants over bone defects in the bony tissue surrounding a dental alveolus (units; Figures 2a & 2b; paragraphs 0021-0022) and a periodontal defect and an implant over the defect (Figure 1a & 1b; paragraphs 0019-0020); the implant materials include various matrix molecules (paragraph 0026) and combination materials that contain growth factor (paragraph 0039); the implants may be membranes, fixation plates, or three dimensional spatial pieces and fixing means (paragraph 0025) (it is noted that the implants taught by Pirhonen would be considered "units applied to the jaw bone" of the instant claims). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the arrangement of Wikesjö, such as the implants of Figure 1b, for implantation into defects of the type illustrated by Pirhonen in Fig. 1a, where the defects are severe enough that the tooth had been lost. Wikesjö implies that if 50% (or 5 mm) of the implant is inserted into the bone, that bone can be stimulated to grow over the exposed part (Figure 1). The exposure of the upper outer surface would have been in the range of 20-180°, and 30-120°, depending on where on the upper opening the measurement is made (see Pirhonen, Fig 1a). It would also have been obvious to cover the area with a unit, such as a membrane or a fixation plate, as illustrated by Pirhonen in Fig. 1 b (with an internally curved surface directed toward the outer thread of the implant, which extends over the implant' surface). The motivation to apply the techniques of Wikesjö in

this specific type of jaw bone defect would be to implant a tooth into this type of defect, without the requirement of extensive and multiple procedure bone grafts. It would also have been obvious to apply different amounts of the GSS material to the regions of the implant that are exposed, in order to direct the stimulation of bone growth in these areas, to give the embodiments of the instant claims. It would also have been obvious to coat the unit with GSS on the surface facing the implant. The motivation would have been to utilize more of the material in the local region where greater bone stimulation is required. There would have been an expectation of success in view of the formation of bone upon application of rhBMP-2 taught by Wikesjö in both augmentation of alveolar bone and dental implant osseointegration (throughout).

Conclusion

25. No claim is allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TPT/
Timothy P. Thomas
Patent Examiner

2/2/08
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER